

K122762

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Microsulis Medical Ltd

SPECIALISTS IN MICROWAVE ABLATION



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NOV 30 2012

A 510(k) Summary

(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92(c))

Date Prepared: 6 September 2012

1. Submitter's name and address

Microsulis Medical Limited
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Parklands Business Park
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Hampshire
PO7 6XP
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FDA Establishment Registration No. 9710493

2. Submitter's telephone number and fax number

Tel: 011 44 2392 240011
Fax: 011 44 2392 240051

3. Contact person:

Mr. Stuart McIntyre – Chief Executive Officer and FDA Official Correspondent

4. Trade/proprietary name of the device:

Trade name – Acculis Accu2i pMTA Applicator and SulisV^{pMTA} Generator
Common name – Microwave Ablation System and Accessories
Classification name - Electrosurgical Cutting and Coagulation Device and Accessories; 21 CFR 878.4400; Procode NEY; Class II

5. Legally marketed predicate device to which substantial equivalence is claimed

Acculis Accu2i pMTA Microwave Tissue Ablation Applicator and SulisV^{pMTA} Generator
Premarket Clearance - K094021



Registered Office
St Stephen's House, 279 Bath Street, Glasgow G2 4JL
Registered in Scotland no. SC328638

Acculis pMTA (Mk2) Applicator with SulisVpMTA
Generator software version 2.1.0 – FDA 510(k) Submission

Common name – Microwave Ablation System and Accessories

Classification name - Electrosurgical Cutting and Coagulation Device and Accessories; 21 CFR 878.4400; Procode NEY; Class II

6. Description of the device that is the subject of this premarket notification

The Acculis Accu2i pMTA (Mk2) Applicator is a surgically invasive, sterile single patient use device that delivers microwave energy for the purpose of the coagulation of soft tissue and represents modifications of the predicate generally to add an intermediate length and reduce system output power range. Based on the modifications within this submission the generator software will also include respective changes to control the output and add multi lingual capabilities.

The Acculis MTA System as a whole includes the (1) Acculis Accu2i pMTA (Mk2) Applicator, (2) Sulis V^{pMTA} Generator with ver. 2.1.0 software, (3) Acculis Local Control Station and (4) optional MTA temperature probes. The Acculis Accu2i pMTA (Mk2) Applicator is a surgically invasive, sterile, single patient use device designed to deliver microwave energy for the purpose of the coagulation of soft tissue.

The Acculis Accu2i pMTA (Mk2) Applicator is available in three lengths 14cm (standard); 19cm (intermediate) and 29cm (long). These lengths permit the user to select the appropriate length to reach the target tissue area. The Acculis Accu2i pMTA (Mk2) Applicator incorporates a bespoke connector which interfaces with the SulisV^{pMTA} Generator via the Acculis pMTA Local Control Station (LCS). The LCS, used to control coolant flow to the applicator, is connected to the generator using a microwave coaxial cable and an integrated 12V power supply and data cable.

The SulisV^{pMTA} Generator is controlled via software version 2.1.0.

7. Explanation of how the device functions

The device releases microwave energy into the target tissue from a tuned microwave emitting array at the distal end of the applicator. The volume of coagulated tissue is regulated by the user by selecting the microwave power level and the duration for which the power will be applied. Guidance is given to the user by way of tables in the Instructions For Use that provide estimated coagulation zone dimensions for differing tissues at differing output powers and durations. Coagulation zones are monitored during treatment using appropriate intra-operative imaging techniques.

The microwave energy is delivered to the emitting array by a coaxial microwave transmission line. The transmission of energy through the cables causes cable heating which is dissipated by the liquid cooling system, controlled by the LCS. The applicator handle comprises a right angled microwave connector and coolant inflow and outflow chambers. These chambers direct the coolant inside the applicator and receive the exhaust flow from the applicator. The handle also

contains connections from the thermocouple that sits in the coolant flow and monitors coolant temperature.

The exhaust coolant is channeled from the applicator handle through an umbilical tube in which the flexible microwave supply coaxial cable sits. This cools the coaxial cable along its length.

The umbilical is terminated with a bespoke connector that integrates the coolant drive piston; coolant feed lines from/to the coolant reservoir and microwave and data connectors.

8. Scientific concepts that form the basis for the device

The device coagulates tissue by the action of the microwave on the tissue as it is absorbed around the emitting array. The array is designed to create a near spherical microwave field in the tissue around the tip. The microwave energy is absorbed by the tissue through the coupling of the microwave to the water dipoles in the tissue. The rapid oscillation of the dipoles results in the transference of energy to the tissue within the microwave field in the form of heat. A zone of thermal conduction extends the coagulated zone beyond the actively microwave heated zone.

The microwave energy decays exponentially with distance from the applicator as the energy of the wave is absorbed. This distance is dictated by the microwave frequency used. This is a constant and is not user controlled. The user can control the rate of development and the size of the thermal coagulation zone using the power level and duration settings.

9. Significant physical and performance characteristics of the device

An efficient tissue heating mechanism is required to achieve the zones of tissue coagulation desired within the operative window available to clinicians. Microwave energy is known for its efficient heating of water dense materials. The chosen frequency of the device, 2.45GHz, allows sufficiently high power levels to be safely delivered within the target tissue. The efficient high pressure liquid cooling system, in which the transmission lines are carried, ensures that the transmission lines do not overheat. Thus the system delivers the desired rapid, yet safe, controlled and confined coagulation of the targeted tissue.

Microwave applicators operate by creating a microwave field in the tissue around the emitting array. No return electrodes or other materials must be applied to the patient for it to function.

The use of bespoke integrated connectors and simple recirculating coolant facilitates the correct setup of the device and minimizes any opportunity for incorrect device preparation.

10. Intended use and indication for use

The Acculis Accu2i pMTA Applicator with the SulisV^{pMTA} Generator software version 2.1.0 is indicated for the intraoperative coagulation of soft tissue.

11. Technological characteristics

The Acculis Accu2i pMTA Applicator is a narrow 2.45GHz liquid cooled microwave antenna configured for percutaneous insertion. The microwave emitting performance of the applicator is unchanged from the predicate design. The LCS is unchanged. The SulisV^{pMTA} Generator software v. 2.1.0 is an upgrade to introduce multi language options for the onscreen text displays and additional fault symbology. The settings in the power control data table referenced by the software reflect revised upper and lower limits. No hardware changes have been made to the SulisV^{pMTA} Generator from the predicate.

12. Performance Testing – Non-Clinical Testing

The performance of the proposed device has been characterized using the same method used for the predicate device. Ex-vivo tissue types were used and coagulations conducted at various power and duration settings. The shape and size of the coagulation zones created were analyzed and compared to that of the predicate. Bench testing also included verification of coolant flow rates, surface temperature, interface compatibility, calorimetry, skin penetration and dimensional characteristics. These tests demonstrate that the performance of the candidate device is equivalent to that of the predicate.

The designed components were individually verified and validated in the course of establishing adherence to the applicable IEC 60601 standards.

13. Performance Testing – Clinical

Determination of substantial equivalence is made on the basis of the non-clinical testing referred to above. Clinical testing has not been conducted for either the proposed or predicate devices for the purposes of establishing equivalence.

14. Substantial Equivalence Discussion

The proposed device represents a modification of the applicator and generator software compared to the predicate device. All other components of the system remain the same. The modifications do not change the intended use, fundamental scientific technology or principle of operation. The energy, the control methodology, the system of cooling, the process of sterilization, the packaging and materials are all unchanged between the predicate and proposed devices. They are ergonomically and visually similar. Non-clinical performance testing demonstrates the proposed device delivers substantially equivalent performance to the predicate device.

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Results of performance testing according to recognized standards and in consideration to the responses posed in FDA's *Guidance on the CDRH Premarket Notification Review Program, 510(k) Decision Making Tree*, the proposed devices are determined to be substantially equivalent to the predicate device.

This concludes the 510(k) Summary



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Microsulis Medical, Limited
% Mr. Stuart McIntyre
Chief Executive Officer and FDA Official Correspondent
Unit 1 and 2 Falson Court
Parklands Business Park
Denmead, United Kingdom PO7 7XP

November 30, 2012

Re: K122762

Trade/Device Name: Acculis Accu2i pMTA Mk2 Applicator with SulisVpMTA Generator
software release 2.1.0

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: NEY

Dated: September 06, 2012

Received: September 10, 2012

Dear Mr. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Acculis Accu2i pMTA Mk2 Applicator
with SulisV^{pMTA} Generator software release 2.1.0

FDA 510(k)
Submission

Indications for Use

510(k) number (if known): K122762

Device name: Acculis Accu2i pMTA Mk2 Applicator with
SulisV^{pMTA} Generator software release 2.1.0

Indications for use: Acculis Accu2i pMTA Applicator with SulisV^{pMTA}
Generator software release 2.1.0 is indicated for
the intraoperative coagulation of soft tissue.

Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
2012.11.29 13:44:38 -05'00'

(Division Sign-off)
Division of Surgical Devices
510(k) Number K122762

Microsulis Medical Ltd 
SPECIALISTS IN MICROWAVE ABLATION

CONFIDENTIAL

Appendices
62836-2-PMN-510(k) Issue A